JKMSCL

JAMMU AND KASHMIR MEDICAL SUPPLIES CORPORATION LTD.
(Public Sector Undertaking of Govt of Jammu & Kashmir)
Corporate Head Office: Plot N-58 Friends Colony, Satyam Road-Marble Market, Trikuta Nagar Jammu.
Corporate Office Kashmir: Opposite, State Motor Garage Deptt. Baramulla National Highway, Bemina
Telephone: 0191-2478842, 0191-2476548 (Jammu).

Subject:-Blacklisting/Debarring of product manufactured by M/s Rhydburg Pharmaceuticals Ltd.

Order No : 70 JKMSCL of 2021
Dated : 06 -04-2021

Whereas, the Drug/Medicine Albendazole Tablet IP 400mg B. Nos. T2005136 D.O.M May/2020 DOE April/2022, T2005135 D.O.M May/2020 DOE April/2022, T2006164 DOM Jun/2020 DOE May/2022, T2006162, DOM Jun/2020 DOE May/2022 and T2006176 DOM Jun/2020 DOE May/2022 was supplied by the Manufacturer M/s Rhydburg Pharmaceuticals Ltd., C-2/3, Sara Industrial Estate Ltd., Village Rampur, Silaquin, Chakrat Raod, Dehradun-248197 Utrakhand to JKMSCL vide Purchase Order No. 10282002877 Dt. 06/03/2020.

Whereas, said batches of the drug were received by Quality Control Section from various Drug Warehouses of JKMSCL for quality control check and were forwarded to various empanelled Laboratories of the JKMSCL for testing/ analysis, after proper coding.

Whereas, batch Nos. T2005135 and T2006164, of Albendazole Tablet IP 400mg were tested by empanelled laboratory of JKMSCL viz M/s Multani Pharmaceuticals Limited., T-10 Okhla Industrial Area, Phase-II, New Delhi - 110020 (India) and both the batches were declared **"NOT OF STANDARD QUALITY"** vide test report Nos. DF2020091866 dated 09/10/2020 and DF2020091868 dated 09/10/2020 respectively.

Whereas, the rest three batch Nos. T2005136, T2006162 and T2006176 of Albendazole Tablet IP 400mg were tested by the empanelled laboratory of JKMSCL viz M/s Shree Krishna Analytical Services Pvt. Ltd. A-5/4, Mayapuri Industrial Area, Phase-II, New Delhi-110064 and all the three batches were declared **"NOT OF STANDARD QUALITY"** vide test report No. SKF-170920009, dated 09/10/2020, SKF-170920006, dated 09/10/2020 and SKF-170920007 dated 09/10/2020 respectively.

Whereas, matter was taken up with the manufacturer, M/s Rhydburg Pharmaceuticals Ltd. C-2/3 Sara Industrial Estate Ltd. Village Rampur, Silaquin, Chakrat Road, Dehradun-248197 Utrakhand,under the captioned subject "drug of all five batches declared **NSQ**" vide letter Nos. JKMSCL / QC/ SGR/ 2020-21/ 578-85, dated 10/10/2020, JKMSCL/QC/SGR/2020-21/586-93 dated 10/10/2020, JKMSCL/QC/SGR/2020-21/635-42 dated 12/10/2020, JKMSCL/QC/SGR/ 2020-21 /650-57 dated 12/10/2020 and JKMSCL/ QC/ SGR/ 2020-21/ 665-72 dated 12/10/2020 and was asked to explain his position and submit required manufacturing details of said batches of drug and recall back the same from various Drug Warehouses of JKMSCL, copy of which was duly endorsed among others to all In-charges of Drug Warehouses for further necessary action at their end.

Whereas, matter was also taken up with Drugs Controller, Dehradun and Drugs Controller, J&K for their information.

Whereas, the said batches of drug were also sent for retesting to the CSIR-IIIM Drug Testing Laboratory Canal Road, Jammu for analysis and were declared of **"STANDARD QUALITY"** vide test report Nos. CSIR-IIIM/DTL/2020/D-00050, dated 10.11.2020, CSIR-IIIM/DTL/2020/D-00051, dated 10.11.2020, CSIR-IIIM/DTL/2020/D-00052, dated 10.11.2020, CSIR-IIIM/DTL/2020/D-00053, dated 10.11.2020 and CSIR-IIIM/DTL/2020/D-00054, dated 10.11.2020.

Whereas, the test reports received from the empanelled laboratories and CSIR-IIIM Drug Testing Laboratory, Canal Road Jammu were contradictory. Accordingly, the In-charge of Drug Testing Laboratory CSIR-IIIM Jammu was asked to clarify his position in this regard.

Whereas, after a gap of 10 days, the Director CSIR-IIIM Drug Testing Laboratory, Canal Road Jammu forwarded the test reports of the said batches of drug, declaring all the five batches of the said drug as **"NOT OF STANDARD QUALITY"** vide report Nos. CSIR / IIIM/DTL/2020/D-00050-I, 10.11.2020 /04.12.2020, CSIR /IIIM/DTL/2020/D-00051-I, 10.11.2020 /04.12.20201, CSIR /IIIM/DTL/2020/D-00052-I, 10.11.2020 /04.12.2020 CSIR /IIIM/DTL/2020/D-00053-I, 10.11.2020 /04.12.2020, CSIR /IIIM/DTL/2020/D-00054-I, 10.11.2020 /04.12.2020, **with the reason "that the said batches of drug are failing in**

Dissolution test which was not previously performed on the said batches of drug".

Whereas, no reply was received from the manufacturer, M/s Rhydburg Pharmaceuticals Ltd. C-2/3 Sara Industrial Estate Ltd. Village Rampur, Silaquin, Chakrat Road, Dehradun-248197 Utrakhand, to whom reminders were served vide letter Nos. JKMSCL/QC/SGR/2020-21/831-837 dated 12/11/2020, JKMSCL /QC/SGR/2020-21/838-844 dated 12/11/2020, JKMSCL /QC/ SGR/ 2020-21/845-851 dated 12/11/2020, JKMSCL/QC/SGR/2020-21 /852-858 dated 12/11/2020 and JKMSCL/QC/SGR/2020-21/859-865 dated 12/11/2020.

Whereas, the matter was again taken up with the manufacturer, M/s Rhydburg Pharmaceuticals Ltd. C-2/3 Sara Industrial Estate Ltd. Village Rampur, Silaquin, Chakrat Road, Dehradun-248197 Utrakhand to give the details of manufacturing of the said batches of drug vide letter No. JKMSCL/QC/SGR/2020/923-29 dated 09.12.2020.

Whereas, all the batches T2005135, T2006164, T2005136, T2006162 & T2006176 of the said drug, were lifted by the Drugs Control officer, DFCO J&K for test / analysis. All the batches of said drug in discussion were declared **"STANDARD QUALITY"** by the Government Analyst Regional Drug Testing Laboratory, Dalgate Srinagar vide test report No. L/DA/2020-21/1274, dated 21.01.2021, L/DA/2020-21/1275, dated 21.01.2021, L/DA/2020-21/1277, dated 21.01.2021, L/DA/2020-21/1276, dated 21.01.2021, and L/DA/2020-21/1278, dated 21.01.2021 respectively.

Whereas, letter vide No. JKMSCL/QC/J/2021/6292-99 Dt. 09-02-2021 with the reminder vide no. JKMSCL/QC/J/2021/6337-44 Dt. 11-02-2021 in reference to DA/K/1556-57 Dt. 03-02-202, Government Analyst Regional Drug Testing Laboratory, Dalgate Srinagar was requested for "dissolution parameter included amended in 2019 as part of testing parameter as per Indian Pharmacopoeia Commission Ghaziabad" with regard to the all five batches of the drug in question.

Whereas, again all the batches T2005135, T2006164, T2005136, T2006162 & T2006176 of the said drug, were tested for dissolution test as per 2019 amended as part of testing parameter as per Indian Pharmacopoeia Commission Ghaziabad by the Government Analyst Regional Drug Testing

Laboratory, Dalgate Srinagar and all the batches were declared **"NOT OF STANDARD QUALITY"** vide test report No. *L/DA/2020-21/1570, dated* 08.03.2021, L/DA/2020-21/1568, dated 08.03.2021, *L/DA/2020-21/1571, dated* 08.03.2021, L/DA/2020-21/1569, dated 08.03.2021, and *L/DA/2020-21/1567,* dated 08.03.2021 respectively for the reasons that " **The sample does not conform to IP with respect to the test of Dissolution**" *vide government* Analyst, Drug Testing Laboratory, Dalgate Srinagar letter No. *DA/K/D-T/1867-70* Dt. 08-03-2021 enclosed with five test report on Form13.

Whereas, the manufacturer Rhydburg Pharmaceuticals Ltd. despite reminders has not bothered to reply till date.

Whereas, **disciplinary committee of JKMSCL constituted for the purpose submitted its recommendations on dated 22-12-2020 &** addendum **dated 17-3-2021** with the following recommendation:-

As per the policy for Blacklisting/ Debarring of Product or Company under clause-4 read with sub-clause-4.6

"If three batches of a particular item supplied under a tender tenure by the supplier are declared as Not of Standard Quality during its entire shelf life by an empanelled lab or Govt. Lab in test for assay and /or in any other parameter(s) and if such failures are further confirmed by another empanelled lab or Govt. Lab during its entire shelf life, the particular item of the drug shall be liable for blacklisting for a period of not less than 2(Two) years."

The action as per "Policy for Blacklisting/Debarring of Product or Company" under clause-4, on account of Quality failure of Drugs and Medicines" read with sub-clause 4.6 may be taken against the manufacturer i.e. M/s Rhydburg Pharmaceuticals Ltd. C-2/3 Sara Industrial Estate Ltd. Village Rampur, Silaquin, Chakrat Raod, Dehradun-248197 Utrakhand.

Whereas, the matter was examined in light of above quality testing report and recommendation of the committee, the competent authority has decided to take necessary action in the matter in terms of para 4.6 of Procedures and Policies/Guidelines (book) regarding Policy for blacklisting/debarring of product of company.

Now, therefore, it is hereby ordered that the Product Tablet Albendazole IP 400mg manufactured by M/s Rhydburg Pharmaceuticals Ltd. C-2/3 Sara Industrial Estate Ltd. Village Rampur, Silaquin, Chakrat Raod, Dehradun-248197 Utrakhand is hereby debarred/blacklisted from JKMSCL for 02(Two) years with immediate effect.

sd/-
Managing Director
J&K Medical Supplies Corporation Ltd.

No. JKMSCL/Adm/BL/16/2021/7377-83
Copy to the:

Dated:06-04-2021

1. Financial Commissioner to Government, Health and Medical Education Department, Civil Secretariat, Jammu.
2. Financial Advisor/Chief Account Officer, JK, Medical Supplies Corporation Ltd.
3. General Manager-(P&S), J&K Medical Supplies Corporation Ltd.
4. In-charge Quality Control Cell, J&K Medical Supplies Corporation Ltd.
5. Incharge Medical Officers Drug Ware Houses
6. PA to Managing Director, J&K Medical Supplies Corporation Ltd.
7. M/s Rhydburg Pharmaceuticals Ltd. C-2/3 Sara Industrial Estate Ltd. Village Rampur, Silaquin, Chakrat Raod, Dehradun-248197 Utrakhand

06.04.21
(Saleem Beigh),KAS
General Manager (Adm)
J&K Medical Supplies Corp. Ltd
Jammu